Dissenting Views

of

Representatives John D. Dingell, Henry A. Waxman, Edward J. Markey, Rick Boucher, Edolphus Towns, Frank Pallone, Jr., Bobby L. Rush, Anna G. Eshoo, Bart Stupak, Eliot L. Engel, Albert R. Wynn, Gene Green, Ted Strickland, Diana DeGette, Lois Capps, Tom Allen, Jan Schakowsky, Hilda L. Solis, and Tammy Baldwin

on

H.R. 4157, the "Better Health Information System Act of 2006"

Summary

H.R. 4157, as amended and reported by the Committee on Energy and Commerce, is inadequate to effectively move the U.S. healthcare system into an electronic age and adopt health information technology, such as electronic health records, that will enable providers to communicate with each other to achieve administrative efficiencies and improve care. The bill does not include sufficient funding to enable providers to adopt and implement systems in their offices. Instead, it undermines existing fraud and abuse laws in the name of spreading health information technology. And, even though moving to an electronic age for healthcare records will make personal information more vulnerable to breach and theft, the bill fails to protect the privacy of patient medical information.

The Minority offered a number of amendments in an effort to (1) provide funding for healthcare providers to purchase and adopt health information technology without undermining protective fraud and abuse laws; (2) improve the quality of care, care coordination, and patient access to information; (3) allow providers, labs, and others in the healthcare system to communicate electronically with each other ("interoperability"), and (4) protect the privacy of patient's information in a new world where information will be maintained electronically. These amendments were rejected on party-line votes.

It is particularly disappointing that a bipartisan Senate bill on health information technology that passed the Senate unanimously on November 18, 2005, has been ignored by the Committee as a starting point for discussions. Instead, Republican colleagues chose to consider a highly partisan bill, greatly reducing the likelihood of enactment of health IT legislation this Congress.

<u>Democrats Offered a Substitute Consisting of the Bipartisan Senate Legislation Along with</u> Privacy Protections

Representatives Pallone and Gonzalez offered a substitute that included the text of the Senate bill, S. 1418, a bipartisan bill that passed the Senate unanimously on November 18, 2005, along with protections to ensure privacy of patient medical records. Unlike the Committee bill, the Democratic substitute would have ensured the rapid adoption of interoperable health information technology without exposing Federal health programs to fraud. Its stronger standards and guaranteed funding would more rapidly move the U.S. healthcare system to the electronic age.

The Democratic substitute codifies the Office of the National Coordinator for Health Information Technology and assigns it duties, including the adoption of interoperability standards allowing for electronic communication between providers, plans, and others. It requires that the Federal Government purchase health information technology that meets interoperability standards. It also includes funding in the form of grants and loans for providers and regional collaboratives to buy and implement health information technology. The technology must meet standards of interoperability, as well. It requires the creation of a voluntary certification process for technology sold by vendors allowing providers to identify whether a product meets their needs and the needs of their patients before purchasing it. It does not make exceptions to the Stark self-referral and anti-kickback fraud and abuse laws, but instead leverages private dollars for a revolving loan fund that would not create a conflict of interest between providers. The substitute also includes privacy and security protections offered by Representative Markey in his privacy amendment described below. It was defeated on a party-line vote.

The Legislation Fails to Protect the Privacy of Medical Records

H.R. 4157 does not include adequate protections to ensure the privacy of patient personal medical information. The expanded adoption and use of technology to enable electronic exchange of information places larger amounts of personally-sensitive data at risk of disclosure or breach. For the successful adoption of health information technology, patients will need assurances their medical records are secure. President Bush has acknowledged this need, noting,

"One thing is the federal government has got to make sure the privacy rules are strong. You're going to hear us talk about medical -- electronic medical records. And that's exciting. But it's not so exciting if you're a patient who thinks somebody could snoop on your records, to put it bluntly.... ...for those people -- there's a lot of people in America who say, good, I want there to be good information technology in the health care field, I just don't want somebody looking at my records unless I give them permission to do so. And I fully understand that. And your records are private, if that's the way you want them to be."

The bill, however, fails to include adequate protections for privacy, merely affirming the limited protections in the current law, the Health Insurance Portability and Accountability Act (HIPAA).

The HIPAA privacy rule, however, is not comprehensive and does not include provisions to adequately protect privacy in an electronic healthcare world. For example, the existing Federal law now only directly applies to some providers, health plans, and health information clearinghouses, but does not apply to anyone else who could receive sensitive health information, such as anyone the provider contracts with, or electronic health records companies. HIPAA also

¹ President Bush Touts Benefits of Health Care Information Technology; Department of Veterans Affairs Medical Center, Baltimore, Maryland, April 27, 2004. (www.whitehouse.gov/news/releases/2004/04/20040427-5.html)

does not require consent for the use or disclosure of health information for treatment, payment, or healthcare operations. This means, for example, that companies could use sensitive, individual information for fundraising.

Current law privacy rules under HIPAA, which would be maintained under the bill, do not require that the person be notified if there is a breach of data where individually-identifiable health information is lost, stolen, or used for an unauthorized purpose. This can include the accidental or erroneous disclosure of individually identifiable health information or the purposeful breach (hacking, theft) of a computer system to access information. And, while HIPAA allows for civil and criminal penalties to be assessed on violators by the Government, despite 19,420 grievances filed so far, not one entity has been assessed civil penalties; only two criminal cases have been prosecuted.

Moreover, HIPAA does not allow an individual who has been harmed to pursue enforcement or seek damages; only the Government is permitted to do that. And because the privacy rule applies only to groups that misuse or disclose health information, such as providers, health plans, and health information clearinghouses, there can be no direct penalties assessed against anyone other than these groups. HIPAA does permit States to have more protective privacy laws and a number of States have laws that address these concerns.

Representatives Markey and Capps offered an amendment to address these privacy and security concerns. Their amendment (1) requires patient consent to share personal health information electronically and allows patients to control access to their sensitive electronic health information; (2) applies protections to any individual in possession of personal health information; (3) allows individuals to get redress when their privacy is breached; (4) requires notification to individuals if their information is violated; (5) requires reasonable safeguards, such as encryption of data; and (6) does not preempt more protective State laws. The Markey-Capps amendment was defeated on a party-line vote.

The Legislation Fails to Provide Adequate Resources to Acquire Health Information Technology

H.R. 4157, as amended and reported by the Committee, provides an extremely limited amount of the funding necessary to encourage physicians, hospitals, and other providers to invest in technology. The bill authorizes \$40 million over 2007 and 2008 for integrated healthcare systems serving uninsured, under-insured, and medically under-served individuals, and also to small physician practices. By contrast, S. 1418, which passed the Senate unanimously, authorized \$652 million over the 2006-2010 period for health information technology.

The lack of sufficient funding to enable providers to adopt health information technology is a critical flaw in the legislation and will make it unlikely that this bill will initiate a large-scale movement to electronic provider communication and improved quality and more coordinated care. A number of Democratic amendments were offered that would have provided substantial funding for IT in order to encourage faster and more comprehensive adoption of such systems. Representatives Brown and Gonzalez offered an amendment that would ensure all providers would be eligible for grants, Medicare add-on payments, and low-interest loans; Representative

Stupak offered an amendment focused on rural providers; and Representatives Wynn, Rush, Solis, Schakowsky, and Engel offered an amendment to address the needs of safety net providers. The amendments were all defeated along largely party-line votes.

The Legislation Opens New Opportunities for Fraud and Abuse

Instead of assisting the funding of health information technology, H.R. 4157 loosens current fraud and abuse laws to allow hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations to give free health information technology, maintenance, service, training, and more to other providers.

These existing anti-fraud laws, known as the Stark self-referral and anti-kickback laws, protect Medicare and Medicaid, as well as patients against biased decision-making by doctors, and ensure that doctors are not referring patients to a specific hospital or other provider because of free gifts they are receiving. While it is important to leverage private sector dollars for the adoption of health information technology, it can be done without increasing the possibility of fraud and abuse. H.R. 4157, on the other hand, provides the broad waivers to the law, which present particular problems:

<u>First</u>, allowing a provider to give valuable free goods and services to another may influence decision-making in favor of the donor. In fact, the Congressional Budget Office noted in their analysis of the fraud loopholes in the Committee on Ways and Means legislation that while the language prohibits explicit *quid pro quo*, in many instances it would be implicit and assumed, resulting in fraudulent behavior.²

Second, the exemption does not require that the donated technology meet interoperability standards. Because a hospital can provide a physician with free technology that only works with the hospital's own technology, this allows the creation of technology silos across the country -- areas where a physician may only be able to electronically communicate with the hospital that gave the physician the free technology, and no one else, including other hospitals or the Government. This runs directly contrary to promoting technology that will allow providers across the country to communicate with each other.

Third, there is no sunset on the provision, meaning that even when technology becomes very inexpensive, as most technology eventually does, the exemption and potential for abuse would still exist because hospitals will still be allowed to influence other providers with support and maintenance services.

<u>Fourth</u>, although the exemptions do not permit a hospital to condition the donation of technology to a doctor on the receipt of referrals, a hospital is allowed to take into account the volume and value of referrals a physician provides to the hospital in determining to whom to

²Congressional Budget Office letter to Committee on Ways and Means Ranking Member Charles B. Rangel on H.R. 4157, June 15, 2006.

donate technology. This means the hospital could choose to reward the physicians that give the hospital its most valuable referrals, such as those with a high percentage of insured patients, and thus implicitly punish the others.

<u>Fifth</u>, the technology a hospital may give a physician may not be the best choice or fit for the physician, but without other incentives or funding to help the doctor, the doctor may have no choice but to accept the technology that is offered or remain a paper-based practice.

<u>Sixth</u>, the definition of health information technology and services is broad, making the potential for fraud and abuse greater.

Representative Pallone offered an amendment to provide direct funding to providers through grants and loans that leverage private sector dollars while reinstating the current law fraud and abuse provisions. The amendment was defeated on a party-line vote.

The Legislation Fails to Achieve Interoperability of Health Information Systems

H.R. 4157, as amended and reported by the Committee, requires the National Coordinator to endorse standards for electronic communications that would allow providers, health plans, and others to communicate with each other by August 2009, or earlier if required under the schedule the National Coordinator establishes. The bill, however, does not require the adoption of standards in the key areas of laboratory information, drug prescribing, clinical research, and ambulatory and inpatient electronic health records, and thus fails to guarantee national standards in these critical areas. Instead, the bill leaves the National Coordinator full discretion as to what standards to adopt.

The bill also does not require the Federal Government to provide a leadership role by incorporating the standards of interoperability in its use of health information technology or purchases of health information technology. Similarly, no other providers or health plans are required to incorporate the use of the standards, nor are incentives included to encourage the use of the standards. The bill merely requires the Federal Government to receive information electronically in a format that meets the standards. Therefore, the Government would not need to implement or use all the standards for electronic communication, therefore allowing fiefdoms where only a handful of providers can communicate with each other electronically.

Representative Eshoo offered an amendment to require the adoption of standards for key areas of health information including, at a minimum, laboratory information, drug prescribing, clinical research, and ambulatory and inpatient electronic health records within 18 months of the enactment of this act. This amendment also requires the Secretary of Health and Human Services to ensure that any purchases of health information technology or systems by Federal health programs meet the national standards of interoperability developed by the Government national task force. Finally, it requires the Federal Government to develop a voluntary certification process allowing buyers of health information technology to know about the system

they are purchasing and whether it meets standards of interoperability. This would have encouraged an informed marketplace where providers and others purchasing hardware and software could assess more fairly and easily which technology best met their needs. This amendment failed on a party-line vote.

Conclusion

The reported bill fails to (1) ensure providers have sufficient resources and incentives to acquire health information technology; (2) require the development of standards to allow electronic communication among providers in the key areas of lab data, prescription drug data, research, and ambulatory and inpatient data in a timely fashion; (3) protect patients and the taxpayers against fraud and improper kickbacks; and (4) protect patient privacy in this new electronic world being promoted in the bill. For those reasons, we oppose H.R. 4157, as reported.

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